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The US Food and Drug Administration cleared for marketing the Xpert Carba-R Assay, an infection control aid that tests patient specimens to detect specific genetic markers associated with bacteria that are resistant to Carbapenem antibiotics.

Carbapenem antibiotics are widely used in hospitals to treat severe infections.

These resistant organisms are commonly referred to as Carbapenem-resistant Enterobacteriaceae, or CRE, and have been reported in almost all states within the US.

"By using a specimen taken directly from a patient to test for the presence of genetic markers, hospitals can more quickly identify these dangerous bacteria resistant to certain antibiotics," said Dr Alberto Gutierrez, director of the FDA's Office of In Vitro Diagnostics and Radiological Health within the Center for Devices and Radiological Health.

Current methods to identify colonization with CRE or other resistant organisms rely on growing bacteria from fecal material in cultures, which are then subjected to antimicrobial susceptibility testing to determine in vitro susceptibility to antimicrobial agents.

Bacterial culture methods and susceptibility testing may take up to four days, and additional testing is often also required to confirm that carbapenemase, an enzyme that inactivates carbapenem antibiotics, is present.

The Xpert Carba-R Assay tests specimens directly taken from patients, which are usually obtained by rectal swabs, for the presence of five different genetic markers that are associated with carbapenemase, the enzyme produced by CRE.

The Xpert Carba-R Assay is intended as an aid in infection control and can be used in conjunction with other clinical and laboratory findings.

Although the Xpert Carba-R Assay tests for the most prevalent carbapenemase genes associated with resistance to carbapenem antibiotics, it does not detect the bacteria, carbapenemase activity or other possible non-enzymatic causes of

carbapenem resistance. The Xpert Carba-R Assay tests only for genetic material.
The Xpert Carba-R Assay also does not detect all types of carbapenemase genes, and it is important to recover bacteria for accurately tracking the spread of carbapenem resistance.

Labs should continue to perform standard bacterial culture in conjunction with the Xpert Carba-R Assay.

In addition, concomitant cultures are necessary to recover organisms for epidemiological typing, antimicrobial susceptibility testing, and for confirmatory bacterial identification.

According to the Centers for Disease Control and Prevention, CRE infections most commonly occur in people with exposure to health care settings, like hospitals and long-term care facilities.

Because of this, these types of infections often occur among patients who are receiving treatment for other serious conditions. Patients whose care requires devices like ventilators, urinary catheters, or intravenous catheters, and patients who are taking long courses of certain antibiotics are among those at risk for CRE infections.

CRE are usually resistant to many other antibiotics in addition to carbapenems, and several CRE outbreaks of these highly resistant bacteria have been reported in the US.

When bacteria become resistant to carbapenems, few treatment options may remain. Some CRE bacteria have become resistant to almost all available antibiotics and present a significant public health threat.

The FDA's decision to provide clearance was based on data from two clinical studies.

A prospective study used rectal swabs from 755 patients in hospitals or long-term care facilities to compare results from the Xpert Carba-R Assay with results from reference cultures and automated real-time polymerase chain reaction (PCR) sequencing.

A second study designed to test the clinical performance of the Xpert Carba-R Assay used 432 rectal swabs that were artificially prepared with specific concentrations of bacteria containing the genes detected by the test.

The results of these studies demonstrated similar performance between the Xpert Carba-R Assay and culture method.

The Xpert Carba-R Assay is manufactured by Cepheid, located in Sunnyvale, California, USA.

The FDA, an agency within the US Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices.

The Agency also is responsible for the safety and security of our nations' food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.